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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,896	08/31/2001	David Botstein	P2548P1C19	5992

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EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/944,896	BAKER ET AL.	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-35 and 38-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *32-34* is/are allowed.

6)☒ Claim(s) *25-31,35 and 38-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 19, 2004 has been entered.

Change of Inventorship

2. The request to correct inventorship filed August 23, 2004, has been entered.

Submission of claims

3. Two sets of claims were filed August 19, 2004, one claim set containing claims 1-20, and the other claim set claims 25-41. Because claims 1-20 had previously been canceled, the Examiner assumes the submission of claim set 1-20 was a mistake, and they will not be examined. If Applicants intend otherwise, it is requested that Applicants respond to that effect in response to this office action.

Claims Status

4. Claims 22-35 and 38-41 are pending in the instant application. Claim 35 has been amended and claims 44 and 43 have been canceled as requested by Applicant in the Paper filed August 19, 2004.

All claims are currently under examination.

Withdrawn Objections and Rejections

5. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

New Objections and Rejections

Claim Objections

6. Claim 35 is objected to because of the following informalities: in sections a-d, the claim recites "a nucleic acid sequence **of** the polypeptide shown in Figure 20…" . While not indefinite, it would clarify the claim if amended to contain the same language as other claims, which would be "a nucleic acid sequence **encoding** the polypeptide shown in Figure 20…".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have amended the claim to include three different high stringency conditions; however, parts (i) and (ii) do not recite any wash conditions, which are critical to the blots obtained. Inclusion of the wash conditions in part (iii) in parts (i) and (ii) would overcome the rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 27, 34, 35 and 38-41 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants' referral to the deposit in the specification is an insufficient assurance that all of the conditions of 37 CFR sections 1.801 through 1.809 have been met. Specifically, the deposit statement is not complete. See MPEP Chapter 2408 Term of Deposit 37 CFR 1.806. Term of deposit. "A deposit made before or during pendency of an application for patent shall be made for a term of at least thirty (30) years and at **least five (5) years after the most recent request for the furnishing of a sample of the deposit** was received by the depository. In any case, samples must be stored under agreements that would make them available beyond the enforceable life of the patent for which the

deposit was made."

An affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the deposit shall be made for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposit was received by the depository, would satisfy the deposit requirement made herein.

Maintained rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 25-31, 35 and 38-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record in the previous Office Actions, Paper No. 10, at pages 6-8, Paper No. 12 at pages 8-9, the paper mailed April 19, 2004 at pages 3-5, and below.

Applicants traverse the rejection on pages 17-22 of the response, and disagree with the Examiner's analysis of claim 1 of Example 11 from the Written Description Training Materials. Applicants assert that the claims of the present application are directed to nucleic acids that have the characteristic of being amplified in lung or colon tumors, and as such, the claims are supported by a diagnostic utility. Applicants' arguments have been fully considered but are not deemed persuasive. Because the claims encompass nucleic acids that encode the protein of SEQ ID NO: 50, or encode polypeptides having at least 95% or 99% sequence identity to the polypeptide of SEQ ID NO: 50 and are amplified in lung or colon tumors, the claims encompass naturally occurring nucleic acids that are allelic variants of the nucleic acid of SEQ ID NO: 49. The instant disclosure of a single nucleic acid encoding a polypeptide, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera.

Applicants also disagree with the Examiner that Claim 27 is similar to Claim 2 in Example 11, and assert that Claim 27 is directed to the wild type DNA sequence disclosed in the specification and that Claim 2 in Example 11 is not applicable to claim 27, which was also not previously rejected. Applicants also traverse rejection of claim 25, and assert that the present application sets forth distinguishing identifying characteristics that are sufficiently detailed to show that the applicant was in possession of the claimed invention. Applicants on page 19 cite Amgen, Inc. V. Chugai Pharmaceutical as support that the written description requirement has been satisfied because they have disclosed a combination of identifying characteristics sufficient to distinguish the claimed invention from other materials, and assert that those of skill in the art, reading the specification, would appreciate that the invention of SEQ ID NO: 49 was not limited to only this sequence, but that the inventors contemplated and described a genus of sequences with at least 95% sequence identity to SEQ ID NO: 49, and that the specification discloses methods of making substitutions as well as substitutions themselves that could be used to obtain a nucleic acid sequence variant of the claimed invention. Applicants further assert that the claimed nucleic acid variants have the characteristic of being amplified in lung or colon tumors, which distinguishes members of the claimed genus from other nucleic acids, and that the specification teaches an assay for identifying and isolating the nucleic acids of the claimed invention. Finally, Applicants disagree with the Examiner that the claims are limited to naturally occurring and not engineered nucleic acids, and assert that the claims do not require that the claimed nucleic acid be isolated from lung or colon tumors, but that they require that claimed nucleic acid to have the characteristic of being amplified in lung or colon tumors.

Applicants' arguments have been fully considered but are not deemed persuasive. Claims 27-31 were mistakenly omitted from the previous rejection, but are rejected because they encompass a nucleic acid which encodes the polypeptide of SEQ ID NO: 50, and so encompass allelic variants, which have not been described. While it is acknowledged that the claims are not limited for the nucleic acid to be isolated from tumor tissue, and that one of skill in the art could make an engineered nucleic acid that corresponds to a naturally occurring variant that is amplified in lung and colon tumors, the point is that it is not predictable what those naturally occurring variants would look like. None have been disclosed. Additionally, claims 25, 26 and 38-40 are not limited to nucleic acid sequences that are 95% or 99% identical to the nucleic acid sequence of SEQ ID NO: 49, as asserted by Applicants in the response on page 20, but encompass nucleic acids encoding a polypeptide having at least 95% or 99% sequence identity to the polypeptide of SEQ ID NO: 50, which is a broader genus. Although allelic variants of the nucleic acid of SEQ ID NO: 49 probably exist and one of skill in the art would know how to screen and isolate them, this does not provide adequate written description for the sequences themselves. The combination of sequence identity to a particular sequence and functional characteristic of being amplified in lung or colon tumors does not provide not provide adequate written description for the sequences, because one of skill in the art could not predict what such naturally occurring sequences would look like. This situation differs from one in which a claimed nucleic acid encoding a protein 95% identical to a specific sequence and possessing a specific activity. Such a claim would have adequate written description, because one of skill in the art could engineer proteins and screen them for activity. However, because the instant claims

require that the nucleic acid variants be amplified in lung or colon tumors, one of skill in the art would need to know what those naturally occurring sequences are.

It is believed that all pertinent arguments have been answered.

Conclusion

10.1 Claims 32-34 are allowed.

10.2 Claims 25-31, 35 and 38-41 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at (571) 272-0961.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara

Eileen B. O'Hara, Ph.D.

Patent Examiner

EILEEN B. O'HARA
PATENT EXAMINER